# TOP-LEVEL RADIOLOGICAL, NUCLEAR, AND PROCESS SAFETY STANDARDS AND PRINCIPLES FOR THE RPP WASTE TREATMENT PLANT CONTRACTOR



U.S. Department of Energy Office of River Protection Richland, Washington

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# **PREFACE**

As directed by Congress in Section 3139 of the *Strom Thurmond National Defense Authorization Act for Fiscal Year 1999*, the U.S. Department of Energy (DOE) established the Office of River Protection (ORP) at the Hanford Site to manage the River Protection Project (RPP), formerly known as the Tank Waste Remediation System. ORP is responsible for the safe storage, retrieval, treatment, and disposal of the high level nuclear waste stored in the 177 underground tanks at Hanford.

The initial concept for treatment and disposal of the high level wastes at Hanford was to use private industry to design, construct, and operate a Waste Treatment Plant (WTP) to process the waste. The concept was for DOE to enter into a fixed-price contract for the Contractor to build and operate a facility to treat the waste according to DOE specifications. In 1996, DOE selected two contractors to begin design of a WTP to accomplish this mission. In 1998, one of the contractors was eliminated, and design of the WTP was continued. However, in May 2000, DOE chose to terminate the privatization contract and seek new bidders under a different contract strategy. In December 2000, a team led by Bechtel National, Inc. was selected to continue design of the WTP and to subsequently build and commission the WTP.

A key element of the River Protection Project Waste Treatment Plant (RPP-WTP) is DOE regulation of safety through a specifically chartered, dedicated Office of Safety Regulation (OSR). The OSR reports directly to the ORP Manager. The regulation by the OSR is authorized by the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of the River Protection Project Waste Treatment Plant Contractor* (DOE/RL-96-25) (referred to as the Policy) and implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, Process Safety Regulation of the RPP-WTP Contractor* (DOE/RL-96-26) (referred to as the MOA). These two documents provide the basis for the safety regulation of the RPP-WTP at Hanford.

The foundation of both the Policy and the MOA is that the mission of removal and immobilization of the existing large quantities of tank waste by the RPP-WTP Contractor must be accomplished safely, effectively, and efficiently.

The Policy maintains the essential elements of the regulatory program established by DOE in 1996 for the privatization contracts. The MOA clarifies the DOE organizational relationships and responsibilities for safety regulation of the RPP-WTP. The MOA provides a basis for key DOE officials to commit to teamwork in implementing the policy and achieve adequate safety of RPP-WTP activities.

The Policy, the MOA, the RPP-WTP Contract and the four documents incorporated in the Contract define the essential elements of the regulatory program being executed by the OSR. The four documents incorporated into the Contract (and also in the MOA) are as follows:

Concept of the DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor, DOE-96-0005,

DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor, DOE/RL-96-0003,

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor, DOE/RL-96-0006, and

Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for the RPP Waste Treatment Plant Contractor, DOE/RL-96-0004.

DOE patterned its safety regulation of the RPP-WTP Contractor to be consistent with the concepts and principles of good regulation (stability, clarity, openness, efficiency, and independence) used by the Nuclear Regulatory Commission (NRC). In addition, the DOE principles of integrated safety management were built into the regulatory program for design, construction, operation, and deactivation of the facility. The regulatory program for nuclear safety permits waste treatment services to occur on a timely, predictable, and stable basis, with attention to safety consistent with that which would occur from safety regulation by an external agency. DOE established OSR as a dedicated regulatory organization to be a single point of DOE contact for nuclear safety oversight and approvals for the WTP Contractor. The OSR performs nuclear safety review, approval, inspection, and verification activities for ORP using the NRC principles of good regulation while defining how the Contractor shall implement the principles of standards-based integrated safety management.

A key feature of this regulatory process is its definition of how the standards-based integrated safety management principles are implemented to develop a necessary and sufficient set of standards and requirements for the design, construction, operation, and deactivation of the RPP-WTP facility. This process closely parallels the DOE necessary and sufficient closure process (subsequently renamed Work Smart Standards process) in DOE Policy 450.3, Authority for the Use of the Necessary and Sufficient Process for Standards-based Environment, Safety and Health Management, and is intended to be a DOE approved process under DOE Acquisition Regulations, DEAR 970.5204-78, Laws, Regulations and DOE Orders, Section (c). DOE approval of the contractor-derived standards is assigned to the OSR.

The RPP-WTP Contractor has direct responsibility for WTP safety. DOE requires the Contractor to integrate safety into work planning and execution. This integrated safety management process emphasizes that the Contractor's direct responsibility for ensuring that safety is an integral part of mission accomplishment. DOE, through its safety regulation and management program, verifies that the Contractor achieves adequate safety by complying with approved safety requirements.

All documents issued by the Office of Safety Regulation are available to the public through the DOE Public Reading Room at the Consolidated Information Center, Washington State University, Room 101L, Richland, Washington. Copies may be purchased for a duplication fee.

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# TOP-LEVEL RADIOLOGICAL, NUCLEAR, AND PROCESS SAFETY STANDARDS AND PRINCIPLES FOR THE RPP WASTE TREATMENT PLANT CONTRACTOR

# 1.0 INTRODUCTION

# 1.1 Purpose

This document provides a set of top-level radiological, nuclear, and process safety standards and principles prescribed by the U. S. Department of Energy (DOE) for accomplishing the expected level of safety for the River Protection Project Waste Treatment Plant (RPP-WTP). Use of these top-level standards and principles does not provide a blanket waiver to safety regulations that apply to DOE activities; rather they are an additional consideration, specified by DOE, for the identification of the Contractor's radiological, nuclear, and process safety standards and requirements. The Contractor shall employ the top-level radiological, nuclear and process safety standards and principles in two ways. First, the Contractor must address these top-level standards and principles in the standards and requirements identified and recommended by the Contractor. Second, the Contractor shall incorporate the top-level radiological, nuclear, and process safety standards and principles into the recommended standards and requirements.

The top-level radiological, nuclear, and process safety standards and principles in this document are independent of the Contractor's waste processing technology and associated facility design. The standards provided in this document are high-level statements that express DOE's expectations for the performance of important-to-safety activities associated with facility design, construction, pre-operational testing, operation, and deactivation. The safety principles provided in this document are a set of broad statements of ways to achieve the expected level of safety, which represent international experience and perspectives. With due consideration for the hazards related to RPP-WTP program activities, the principles were derived from a number of sources, including the International Atomic Energy Agency's Basic Safety Principles for Nuclear Power Plants, DOE Orders and regulations, DOE Directives, the Code of Federal Regulations governing the U.S. Nuclear Regulatory Commission's (NRC) regulation of commercial nuclear facilities and operations, the Center for Chemical Process Safety's Guidelines for Technical Management of Chemical Process Safety, and the Occupational Safety and Health Administration's regulations and recent programs for which comparable high-level safety requirements were formulated. In recognition of the safety practices unique to process safety, process safety principles specified by DOE are presented as a separate set. The Contractor is expected to achieve efficiency through the elements common to radiological and nuclear safety, and process safety. Radiological and nuclear safety objectives are also included to provide goals for the Contractor to assess the adequacy of radiological and nuclear safety.

# 1.2 Scope

This document shall be used for the identification and recommendation of radiological, nuclear, and process safety standards and requirements. This document and the standards and

requirements apply only to the radiological, nuclear, and process safety regulation of the RPP-WTP Contractor. While the scope of the regulation is predominantly limited to the Contractor's activities from initial design through deactivation, it also must include the Contractor's consideration of site characteristics, its use of site services, and its coordination with DOE Richland Operations Office's integrated emergency response.

# 2.0 RADIOLOGICAL AND NUCLEAR SAFETY STANDARDS

The radiological and nuclear standards in this section are the human dose standards to which all facility activities of the Contractor involving radiological and nuclear hazards must comply. These standards are consistent with radiological exposure limits embodied in DOE and NRC regulations and the perspectives of the International Council on Radiological Protection. The standards presented herein do not include standards for various release pathways and are not necessarily a complete set for human doses. The absence of other standards is not intended to exempt the Contractor from the obligation to comply with all applicable requirements pertaining to limiting exposures to workers and the public.

#### 2.1 Individual

The top-level radiological and nuclear safety standards for workers, co-located workers, and the public for various situations are listed in Table 1. Footnotes to the table refer to the origin of a specific standard. Additional information on terminology, definitions, and methods can be found in those references. As noted in the references, some of the standards cannot be applied independent of other dose contributors located on the Hanford Site.

# 3.0 RADIOLOGICAL AND NUCLEAR SAFETY OBJECTIVES

The safety objectives included in this section are radiological and nuclear safety goals, which if accomplished, should ensure protection of public and worker health and safety. The Contractor should use these objectives to determine (1) the effectiveness in achieving the expected level of safety and (2) the need for additional measures.

# 3.1 General Safety Objectives

# 3.1.1 Operations Risk Goal

The risk, to the population (public and workers) in the area of the Contractor's facility, of cancer fatalities that might result from facility operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks to which members of the U.S. population generally are exposed.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> For evaluation purposes, individuals are assumed to be located within 10 miles of the controlled area.

Table 1. Dose<sup>1</sup> Standards Above Normal Background<sup>4</sup>

Description	Estimated Probability of Occurrence P(yr <sup>-1</sup> )	Worker	Co-located Worker	Public
Normal Events: Events that occur regularly in the course of facility operation (e.g., normal facility operations).	P=1	≤5 rem/yr <sup>2</sup> ≤50 rem/yr any organ, skin, or extremity <sup>2</sup> ≤15 rem/yr lens of eye <sup>2</sup> ≤1.0 rem/yr ALARA design objective <sup>3</sup>	≤5 rem/yr <sup>3</sup> ≤1.0 rem/yr ALARA design objective <sup>3</sup>	≤10 mrem/yr (airborne pathway) <sup>4</sup> ≤100 mrem/yr (all sources) <sup>5</sup> ≤100 mrem/yr <sup>6</sup> ≤25 mrem/yr <sup>7</sup>
Anticipated Events: Events of moderate frequency that may occur once or more during the life of a facility (e.g., minor incidents and upsets).	10 <sup>-2</sup> <p<1< td=""><td>≤5 rem/event<sup>8</sup> ≤1.0 rem/event ALARA design objective<sup>3</sup></td><td>≤5 rem/event<sup>8</sup> ≤1.0 rem/event ALARA design objective<sup>3</sup></td><td>≤100 mrem/event<sup>8</sup></td></p<1<>	≤5 rem/event <sup>8</sup> ≤1.0 rem/event ALARA design objective <sup>3</sup>	≤5 rem/event <sup>8</sup> ≤1.0 rem/event ALARA design objective <sup>3</sup>	≤100 mrem/event <sup>8</sup>
Unlikely Events: Events that are not expected, but may occur during the lifetime of a facility (e.g., more severe incidents).	10 <sup>-4</sup> <p≤10<sup>-2</p≤10<sup>	To be derived <sup>9</sup>	To be derived <sup>9</sup>	≤5 rem/event <sup>10</sup>
Extremely Un- likely Events: 11 Events that are not expected to occur during the life of the facility but are postulated because their consequences would include the potential for the release of significant amounts of ra- dioactive material.	10 <sup>-6</sup> <p≤10<sup>-4</p≤10<sup>	To be derived <sup>9</sup>	To be derived <sup>9</sup>	≤25 rem/event <sup>12</sup> ≤300 rem/event to thyroid <sup>12</sup>

<sup>1.</sup> Dose is assumed to be the committed effective dose equivalent from inhaled radionuclides and any direct radiation from the accident.

<sup>2. 10</sup> CFR 835.202, "Occupational Dose Limits for General Employees," and 10 CFR 20.1201, "Occupational Dose Limits for Adults."

<sup>3. 10</sup> CFR 835.1002(b), "Facility Design and Modification."

<sup>4. &</sup>quot;General Guidelines" column deleted by Revision 3.

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- 5. Proposed Rule 10 CFR 834.102(2), "Airborne Emissions Only, All DOE Sources of Radionuclides," and 40 CFR 61.92, "Public Dose from Emissions of Radionuclides to the Ambient Air from DOE Facilities."
- 6. Proposed Rule 10 CFR 834.101, "Public Primary Dose Limit," and 10 CFR 20.1301(a)(1), "Dose Limits for Individual Members of the Public."
- 7. 10 CFR 835.206, "Limits of Members of the Public Entering a Controlled Area," and 10 CFR 20.1301(b), "Dose Limits for Individual Members of the Public."
- 8. Proposed Rule 10 CFR 834.221, "Public Primary Dose Limit for Radioactive Waste."
- 9. Proposed Rule 10 CFR 60, "Disposal of High-Level Radioactive Waste in Geologic Repositories; Design Basis Events."
- 10. Specific limits were derived and proposed by the Contractor during Part A (≤25 rem/event). The specific derived value is subject to modification through the authorization basis change process described in RL/REG-97-13, *Regulatory Unit Position on Contractor-Initiated Changes to the Authorization Basis*.
- 11. 10 CFR 72.106, "Control Area of an Independent Spent Fuel Storage Installation or Monitored Retrievable Storage Facility."
- 12. They represent the upper bounds on failures or accidents with the probability of occurrence sufficiently high to require consideration in the design.
- 13. 10 CFR 100.10, "Siting Evaluation Factors."

#### 3.1.2 Accident Risk Goal

The risk, to an average individual in the vicinity of the Contractor's facility, of prompt fatalities that might result from an accident should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population generally are exposed.<sup>2</sup>

#### 3.1.3 Worker Accident Risk Goal

(This section was deleted in Revision 3)

# 3.2 Radiation Protection Objective

Ensure that during normal operation radiation exposure within the facility and radiation exposure and environmental impact due to any release of radioactive material from the facility is kept as low as is reasonably achievable (ALARA) and within prescribed limits, and ensure mitigation of the extent of radiation exposure and environmental impact due to accidents.

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<sup>&</sup>lt;sup>2</sup> For evaluation purposes, individuals are assumed to be located within 1 mile of the controlled area.

# 3.3 Technical Safety Objectives

#### 3.3.1 Public Protection

Measures in the design and operation of the facility to protect the public against accident conditions should be evaluated against acceptable guidelines to demonstrate that they perform their intended purpose with high confidence.

#### 3.3.2 Worker Protection

Measures in the design and operation of the facility to protect the workers against accident conditions should be evaluated using an acceptable approach to demonstrate that they perform their intended purpose with high confidence.

#### 3.3.3 Accident Vulnerability Mitigation

Particular care should be taken to identify, evaluate, and prevent and/or mitigate any vulnerabilities to accidents that might, by themselves, result in a release of radioactive material that exceeds acceptable levels.

# 4.0 GENERAL RADIOLOGICAL AND NUCLEAR SAFETY PRINCIPLES

The safety principles presented in this section are fundamental ways to achieve safety, which by experience, have proven to be effective and have become the basis for accepted radiological and nuclear safety practice. Although the experience base for these principles comes largely from the commercial nuclear reactor community, these principles have merit for any nuclear facility. In facilities with hazards much reduced from those of nuclear reactors, measures to accomplish these principles may be less extensive and require less complex approaches than those related to reactor safety. These principles shall be addressed in the standards and requirements identified and recommended by the Contractor.

# 4.1 Overall Principles

#### 4.1.1 Defense in Depth

# 4.1.1.1. Defense in Depth

To compensate for potential human and mechanical failures, a defense-in-depth strategy should be applied to the facility commensurate with the hazards such that assured safety is vested in multiple, independent safety provisions, no one of which is to be relied upon excessively to protect the public, the workers, or the environment. This strategy should be applied to the design and operation of the facility.

#### **4.1.1.2. Prevention**

Principle emphasis should be placed on the primary means of achieving safety, which is the prevention of accidents, particularly any that could cause an unacceptable release.

#### 4.1.1.3. Control

Normal operation, including anticipated operational occurrences, maintenance, and testing, should be controlled so that facility and system variables remain within their operating ranges and the frequency of demands placed on structures, systems, and components important to safety is small.

### **4.1.1.4. Mitigation**

The facility should be designed to retain the radioactive material through a conservatively designed confinement system for the entire range of events considered in the design basis. The confinement system should protect the workplace and the environment.

# 4.1.1.5. Automatic Systems

Automatic systems should be provided that would place and maintain the facility in a safe state and limit the potential spread of radioactive materials when operating conditions exceed predetermined safety setpoints.

# 4.1.1.6. Human Aspects

The human aspects of defense in depth should include a design for human factors, a quality assurance program, administrative controls, internal safety reviews, operating limits (technical safety requirements), worker qualification and training, and the establishment of a safety/quality program.

# **4.1.2** Safety Responsibility

# 4.1.2.1. Safety Responsibility

Direct responsibility for the safety of the facility rests with the Contractor. In no way should this responsibility be diluted by the separate activities and responsibilities of designers, suppliers, constructors, the Office of Safety Regulation (OSR), or independent oversight bodies.

# 4.1.2.2. Safety Assignments

The assignment and subdivision of responsibility for safety should be kept well defined throughout the life of the facility.

# **4.1.2.3.** Site and Technical Support

The Contractor should assure commitments from relevant parties to provide data and services needed to fulfill its safety commitments.

# **4.1.2.4.** Operating Experience and Safety Research

Operating experience and the results of research relevant to safety should be obtained, reviewed, and analyzed, and lessons that are learned should be implemented in the design, construction or modification, and operation of the facility.

#### 4.1.3 Authorization Basis

#### **4.1.3.1.** Authorization Basis

Material that is part of the authorization basis should be established, documented, and submitted to ORP for evaluation and in support of decisions and regulatory oversight. The Contractor should maintain the material current with respect to changes made to the facility design and administrative controls and in the light of significantly new safety information.

# 4.1.4 Safety/Quality Culture

#### 4.1.4.1. Safety/Quality Culture

A safety/quality program should be established that governs the Contractor's actions and interactions of all personnel and organizations engaged in activities related to the facility and emphasizes excellence in all activities. The Contractor should have safety and quality responsibilities specifically identified in its operations.

# 4.1.5 Configuration Management

### **4.1.5.1.** Formal Configuration Management

Formal configuration management should be applied to all facility activities during the program's lifetime to ensure that programmatic objectives related to radiological, nuclear, and process safety are fully achieved. Work should be performed and controlled according to preapproved plans and procedures that clearly delineate responsibilities. Documented records should be retained.

# 4.1.5.2. Contractor Design Knowledge

The Contractor operating organizations should become and remain familiar with the features and limitations of components included in the design of the facility. They should obtain appropriate input from the design organization on pre-operational testing, operating procedures, and the planning and conduct of training.

# 4.1.5.3. Design Documentation

A system should be used to control and maintain accurate as-built drawings during the life of the facility related to radiological, nuclear, and process safety.

#### 4.1.6 Quality Assurance

# 4.1.6.1. Quality Assurance Application

Quality assurance and quality control should be applied throughout all phases and to all activities associated with the facility as part of a comprehensive system to ensure with high confidence that all items delivered and services and tasks performed meet required standards.

# **4.1.6.2.** Established Techniques and Procedures

The Contractor should use well proven and established techniques and procedures supported by quality assurance practices to provide high quality equipment and achieve high quality construction.

# **4.1.6.3.** Operational Quality Assurance Programs

Operational quality assurance and control programs should be established by the Contractor to assist in ensuring satisfactory performance in facility activities important to safety.

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# 4.2 Design, Construction, and Pre-Operational Testing

# **4.2.1** Design

# 4.2.1.1. Safety Design

The facility should be designed for a set of events such as: normal operation, including anticipated operational occurrences, maintenance, and testing; external events; and postulated accidents.

#### 4.2.1.2. Risk Assessment

Acceptable risk analyses should be applied during the design to delineate provisions for the prevention and mitigation, including emergency preparedness and response, of otherwise risk-dominant events.

#### 4.2.1.3. Safety Analysis

A safety analysis should be carried out as required to evaluate the safety performance of the design and identify requirements for operations.

# **4.2.2** Proven Engineering Practices/Margins

#### **4.2.2.1.** Proven Engineering Practices

Safety technologies incorporated into the facility design should have been proven by experience or testing and should be reflected in approved codes and standards. Significant new design features should be introduced only after thorough research and model or prototype testing at the component, system, or facility level, as appropriate.

#### 4.2.2.2. Common-Mode/Common-Cause Failure

Design provisions should be included to limit the loss of safety functions due to damage to several structures, systems, or components important to safety resulting from a common-cause or common-mode failure.

# 4.2.2.3. Safety System Design and Qualification

Structures, systems, and components important to safety should be designed and qualified to function as intended in the environments associated with the events for which they are intended to respond. The effects of aging on normal and abnormal functioning should be considered in design and qualification.

#### 4.2.2.4. Codes and Standards

Codes and standards for vessels and piping should be supplemented by additional measures (such as erosion/corrosion programs and piping in-service inspections) to mitigate conditions arising that could lead to an unacceptable release of radioactivity during the operational life of the facility.

# 4.2.2.5. Criticality

The facility should be designed and operated in a manner that prevents nuclear criticality.

#### **4.2.3 Radiation Protection**

#### 4.2.3.1. Radiation Protection Practices

An acceptable system of radiation protection practices should be followed in the design, construction, and pre-operational testing phases of the facility for the protection of workers and the public.

#### **4.2.3.2.** Radiation Protection Features

At the design stage, radiation protection features should be incorporated to protect workers from radiation exposure and to keep emissions of radioactive effluents as low as reasonably achievable and within prescribed limits.

# 4.2.3.3. Deactivation, Decontamination, and Decommissioning Design

The design of the facility should incorporate provisions to facilitate deactivation and the final decommissioning. The objective of these provisions should be to reduce radiation exposures to Hanford Site personnel and the public both during and following deactivation and decommissioning activities and to minimize the quantity of radioactive waste generated during deactivation, decontamination, and decommissioning.

# 4.2.4 Emergency Preparedness

#### 4.2.4.1. Support Facilities

The facility design should provide additional capability to place and maintain the facility in a safe state following an accident if the normal control areas are expected to become uninhabitable.

# 4.2.5 Inherent/Passive Safety Characteristics

Design features that enhance safety through simplified, inherent, passive or other highly reliable means to accomplish safety functions should be employed to the maximum extent practicable.

#### 4.2.6 Human Factors

#### **4.2.6.1.** Human Error

The possibility of human error in facility operations should be taken into account in the design by facilitating correct decisions by operators and inhibiting wrong decisions and by providing means for detecting and correcting or compensating for error.

# 4.2.6.2. Instrumentation and Control Design

Sufficient instrumentation and control capability should be provided so that under normal operating and postulated accident conditions the operators can diagnose facility conditions, place and maintain the facility in a safe state, and mitigate accidents. If necessary, measures should be provided to protect the operator in the performance of these functions.

# 4.2.6.3. Safety Status

Parameters to be monitored in the control room should be selected and their displays should be arranged to ensure that operators have clear and unambiguous indications of the status of facility conditions important to safety, especially for the purpose of identifying and diagnosing the actuation and operation of a system or components important to safety.

# 4.2.7 Reliability, Availability, Maintainability, and Inspectability

#### **4.2.7.1.** Reliability

Reliability targets should be assigned to structures, systems, and components or functions important to safety. The targets should be consistent with the roles of the structures, systems, and components or functions in different accident conditions. Provision should be made for appropriate testing and inspection of structures, systems, and components for which reliability targets have been set.

#### 4.2.7.2. Availability, Maintainability, and Inspectability

Structures, systems and components important to safety should be designated, designed and constructed for appropriate inspection, testing, and maintenance throughout their operating lives to verify their continued acceptability for service with an adequate safety margin.

# 4.2.8 Pre-Operational Testing

# 4.2.8.1. Testing Program

A pre-operational testing program should be established and followed to demonstrate that the entire facility, especially items important to safety, has been constructed and functions according to the design intent, and to ensure that weaknesses are detected and corrected.

# 4.2.8.2. Operational Systems and Functional Testing Procedures Validation

Procedures for normal facility and systems operation and for functional tests to be performed during the operating phase should be validated as part of the pre-operational testing program.

# 4.2.8.3. Safety Systems Data

During pre-operational testing, detailed diagnostic data should be collected on systems and components important to safety and the initial operating parameters of the systems and components should be recorded.

### 4.2.8.4. Design Operating Characteristics

During the pre-operational testing program, the as-built operating characteristics of process systems, and systems and components important to safety should be determined and documented. Operating points should be adjusted to conform to values in the design basis. Training procedures and limiting conditions for operation should be modified to accurately reflect the operating characteristics of the systems and components as built.

# 4.3 Operation

# **4.3.1** Conduct of Operations

#### 4.3.1.1. Organizational Structure

The Contractor should exert its direct, contractually defined responsibility for the safe operation of the facility through a strong, unambiguous organizational structure.

### **4.3.1.2.** Normal Operations

Operations should be conducted in accordance with approved technical safety requirements and in strict accordance with administrative and procedural controls.

# 4.3.1.3. Emergency Operating Procedures

To provide a basis for suitable operator response to accident conditions, emergency operating procedures should be established, documented and approved.

#### 4.3.1.4. Readiness

The facility manager should ensure that all elements for safe facility operation are in place, including an adequate number of qualified and experienced workers. Minimum requirements also should be set for the availability of staff and equipment.

#### 4.3.1.5. Internal Surveillance and Audits

Internal safety review procedures should be used by the Contractor to provide a continuing surveillance and audit of facility operational safety and to support the facility manager in overall safety responsibilities.

# **4.3.1.6.** Operations Within the Authorization Basis

Operations should be conducted in accordance with approved technical safety requirements. Limiting conditions of operation, limiting control settings, and safety limits should be established as necessary to ensure operation within the authorization basis.

# 4.3.1.7. Access to Technical Safety Support

Throughout the life of the facility, the Contractor should have access to engineering and technical support personnel who are competent in all disciplines important to safety.

#### **4.3.1.8.** Operational Events

Facility management should institute measures to ensure that events relevant to safety are detected and evaluated and that necessary corrective measures are taken promptly and information on them is disseminated. Operational event reports should be prepared and submitted to ORP. The facility management should have access to operational safety experience from other related facilities.

#### 4.3.2 Radiation Protection

# 4.3.2.1. Radiation Practices

An acceptable system of radiation protection practices should be followed in the operational phase for the protection of workers and public.

#### 4.3.2.2. Procedures and Monitoring

The radiation protection staffs of the Contractor's operating organizations should establish written procedures for the control, guidance, and protection of personnel; and routinely monitor facility site radiological conditions; the exposure of facility personnel to radiation; and releases of radioactive effluents.

#### 4.3.2.3. Final Deactivation Plans and Provisions

Deactivation of the facility should be planned. These plans and provisions should incorporate radiation protection practices to protect Hanford Site personnel and the public, both during and following deactivation activities, and waste minimization procedures to reduce the amount of radioactive waste generated during deactivation.

#### 4.3.3 Emergency Preparedness

#### 4.3.3.1. Offsite Measures

Hanford Site and offsite mitigation measures should be provided to substantially reduce the effects of an unacceptable accidental release of radioactive material.

# **4.3.3.2.** Accident Management Strategy

The results of analyses of the response of the facility to accidents with the potential for releases resulting in doses in excess of the U.S. Environmental Protection Agency and the State of Washington emergency clean-up standards, beyond the facility control perimeter (security fence) should be used in preparing guidance on an accident management strategy.

### **4.3.3.3.** Establishment and Continued Exercise of Emergency Plans

Emergency plans should be prepared before the startup of the facility and should be exercised periodically to ensure that protection measures can be implemented in the event of an accident that results in, or has the potential for, unacceptable releases of radioactive materials within and beyond the facility control perimeter. Emergency planning zones defined around the facility should allow for the use of a graded response.

### 4.3.4 Training and Qualifications

#### **4.3.4.1.** Personnel Training

Personnel engaged in activities bearing on facility safety should be trained and qualified to perform their duties.

# 4.3.4.2. Training Programs

Programs should be established for continual training of operations and maintenance personnel to enable them to perform their duties safely and efficiently.

### **4.3.4.3.** Conditions Beyond Design Basis

Operating staff should be trained and retrained in the procedures to follow if conditions exceed the design basis of the facility.

### 4.3.5 Operational Testing, Inspection, and Maintenance

### 4.3.5.1. Operational Testing, Inspection, and Maintenance

Structures, systems, and components important to safety should be the subject of appropriate, regular preventive maintenance, inspection, and testing and servicing when needed, to ensure that they remain capable of meeting their design requirements throughout the life of the facility. Such activities should be carried out in accordance with written procedures supported by quality assurance measures.

# 4.3.6 Security

#### **4.3.6.1.** Security

Adequate provisions for facility security and physical protection of structures, systems, and components important to safety should be provided.

# 4.4 Internal Safety Oversight

# 4.4.1 Safety Review Organization

The Contractor should establish a framework for its safety review organizations that are responsible for assuring the safety of the facility. The separation between the responsibilities of the safety review organizations and those of the other organizations should remain clear so that the safety review organizations retain their independence as safety authorities.

# 4.4.2 Qualified Personnel

Internal safety oversight should be conducted by qualified personnel to ensure that the safety standards are consistently met.

#### 4.4.3 Recommendation for Initiation of Construction

The Contractor should request authorization for construction only after being satisfied by appropriate internal assessments that the main safety issues have been satisfactorily resolved and that the remainder are amenable to solution before operations are scheduled to begin.

# 4.4.4 Unresolved Safety Questions

All facility modifications after operations begin that can affect safety should be assessed by the Contractor for an "unreviewed safety question" and positive determinations submitted to ORP for review.

# 5.0 GENERAL PROCESS SAFETY PRINCIPLES

The safety principles presented in this section are fundamental ways to achieve process safety, which have been proven to be effective in the chemical industry and have become the basis for accepted process safety practice. These principles shall be used to address all process hazards associated with the RPP-WTP facilities. These principles shall be addressed by the Contractor in the standards identified in the Safety Requirements Document. The standards and the controls implementing these standards should be tailored to the significance of the hazard.

# 5.1 Overall Principles

# **5.1.1** Process Safety Management

The Contractor should use a comprehensive process safety management program to eliminate or reduce the incidence, or mitigate the consequences of accidental hazardous chemical releases, process fires, and process explosions. This program should address management practices, technologies, and procedures.

# 5.1.2 Process Safety Objective

Process safety management should confirm that the facility is properly designed, the integrity of the design is maintained, and the facility is operated according to the safe manner intended.

#### **5.1.3** Process Safety Responsibility

The direct responsibility for process safety rests with the Contractor. In no way should this responsibility be diluted by the separate activities and responsibilities of designers, suppliers, constructors, the OSR, or independent oversight bodies.

# 5.2 Process Safety Management Program

# **5.2.1** Process Safety Information

The Contractor should develop and maintain certain important information about the process. This information is intended to provide a foundation for identifying and understanding the process hazards. The process safety information includes, but is not limited to, a summary of material data, a description of each process and its operation, and equipment design data.

The information should confirm that the equipment is appropriate for the operation, that its integrity is maintained, and that it meets appropriate codes and standards.

# 5.2.2 Process Hazard Analysis

The Contractor should perform a process hazards analysis using acceptable industry practices. The process hazards analysis should be appropriate for the complexity of the process and the hazard. The Contractor should consider the effects of engineering and administrative controls, human factors, facility siting, and previous incidents in the hazard analysis. The Contractor should document the results of the hazard analysis including process hazards and possible safety and health effects. The Contractor should submit the results of the hazard analysis to ORP for evaluation and in support of authorization decisions and regulatory oversight.

One of the purposes of the hazard analysis is to evaluate the adequacy of the design and operating procedures. The Contractor should establish a system to address the findings in order to assure that the equipment and procedures provide an adequate degree of protection against accidents.

The Contractor should review and update the hazard analysis periodically to assure that the process hazards analysis is consistent with the current process.

# **5.2.3 Operating Procedures**

The Contractor should develop and implement written operating procedures that provide clear instruction for safely conducting activities consistent with the process safety information. The procedures should address at least the following elements: steps for each operating phase of the process, operating limits, safety and health considerations, and safety systems and their functions.

# 5.2.4 Training

Each operator should be trained in an overview of the process and in the operating procedures. The training should include emphasis on the specific safety and health hazards, operating limits, emergency operations, and safety work practices. The employees should receive refresher training at an appropriate frequency considering the applicable standards and the nature of the hazards.

#### 5.2.5 Subcontractors

The Contractor may engage a subcontractor to perform maintenance, renovations, or specialty work on or adjacent to, the process. The Contractor should inform the subcontractor of potential hazards related to the subcontractor's work and take appropriate measures to ensure the subcontractors provide their workers with appropriate procedures and training necessary for performing their jobs safely.

# 5.2.6 Pre-startup Safety Review

The Contractor should perform a pre-startup safety review for the facility. Pre-startup reviews also should be performed prior to restarting the process after significant modifications have been made to the facility. The pre-startup review should confirm that prior to the introduction of hazardous materials construction and equipment is in accordance with design specifications; safety operating, maintenance, and emergency procedures are in place; an adequate process hazards evaluation has been performed and the recommendations resolved; and training of employees has been completed. The results of this review should be submitted to ORP for evaluation and in support of authorization decisions and regulatory oversight.

# **5.2.7** Mechanical Integrity

The Contractor should implement a mechanical integrity program that includes written procedures, training for maintenance activities, inspection and performance testing of process equipment, and quality assurance measures. The program should include measures to correct deficiencies in equipment that are outside acceptable limits.

Note: A mechanical integrity program is a major and necessary element in a process safety management program because of its importance in ensuring equipment integrity, eliminating potential ignition sources, and determining that equipment is designed, installed, and operating properly.

#### 5.2.8 Hot Work Control

The Contractor should control hot work operations performed in or near the process or facility in order to ensure appropriate safety precautions, including fire prevention and protection, are taken prior to the work.

# **5.2.9** Management of Change

The Contractor should evaluate all planned changes involving the technology of the process and the facility design and operation in order to ensure that the impact on safety is analyzed and acceptable and to determine the need for modifications to operating procedures. The Contractor should establish and implement written procedures to manage changes to process chemicals, technology, equipment, and procedures; and changes to facilities. These procedures should

address the technical basis for the proposed changes, impact of the changes on process safety, modification of the operating procedures, the schedule for proposed changes, and authorization for proposed changes.

# 5.2.10 Incident Investigation

The Contractor should investigate each incident which results in, or could reasonably have resulted in, a major accident. The investigation should be conducted promptly and appropriate corrective measures should be recommended and implemented. The results of the investigation should be submitted to ORP for evaluation and in support of regulatory oversight.

# 5.2.11 Emergency Planning and Response

The Contractor should establish and implement an emergency action plan in accordance with the applicable standards.

# **5.2.12** Compliance Audits

The Contractor should conduct a compliance audit periodically to certify that the procedures and practices developed under the process safety management program are adequate and are being followed. The frequency of compliance audits is based on the applicable standards and the nature of the process hazards. The Contractor should promptly determine and document an appropriate response to each finding of the compliance audit. The results of the audits should be available to ORP in support of regulatory oversight.

#### 6.0 REFERENCES

10 CFR 100.10, "Siting Evaluation Factors," Code of Federal Regulations, as amended.

10 CFR 20.1201, "Occupational Dose Limits for Adults," *Code of Federal Regulations*, as amended.

10 CFR 20.1301(a)(1), "Dose Limits for Individual Members of the Public," *Code of Federal Regulations*, as amended.

10 CFR 20.1301(b), "Dose Limits for Individual Members of the Public," *Code of Federal Regulations*, as amended.

10 CFR 60, "Disposal of High-Level Radioactive Waste in Geologic Repositories; Design Basis Events" (Proposed Rule), 60 FR 15180, *Federal Register*, March 22, 1995.

10 CFR 72.106, "Control Area of an Independent Spent Fuel Storage Installation or Monitored Retrievable Storage Facility," *Code of Federal Regulations*, as amended.

10 CFR 834.101, "Public Primary Dose Limit" (Proposed Rule), 60 FR 47498, Federal Register, September 13, 1995.

10 CFR 834.102(2), "Airborne Emissions Only, All DOE Sources of Radionuclides" (Proposed Rule), 60 FR 47498, *Federal Register*, September 13, 1995.

10 CFR 834.221, "Public Primary Dose Limit for Radioactive Waste" (Proposed Rule), 60 FR 47498, *Federal Register*, September 13, 1995.

10 CFR 835.1002(b), "Facility Design and Modification," *Code of Federal Regulations*, as amended.

10 CFR 835.202, "Occupational Dose Limits for General Employees," *Code of Federal Regulations*, as amended.

10 CFR 835.206, "Limits of Members of the Public Entering a Controlled Area," *Code of Federal Regulations*, as amended.

40 CFR 61.92, "Public Dose from Emissions of Radionuclides to the Ambient Air from DOE Facilities," *Code of Federal Regulations*, as amended.

American Institute of Chemical Engineers (AIChE), *Guidelines for Technical Management of Chemical Process Safety*, Center for Chemical Process Safety, 1989.

EH-12-94-01, Methods for the Assessment of Worker Safety Under Radiological Accident Conditions at Department of Energy Nuclear Facilities, U.S. Department of Energy, 1994.

International Atomic Energy Agency, *Basic Safety Principles for Nuclear Power Plants*, International Nuclear Safety Advisory Group 75-INSAG-3, 1988.

# 7.0 LIST OF TERMS

DOE U.S. Department of Energy

NRC U.S. Nuclear Regulatory Commission

ORP Office of River Protection
OSR Office of Safety Regulation

RPP-WTP River Protection Project Waste Treatment Plant

# 8.0 GLOSSARY<sup>3</sup>

**acceptable release**: The release of radioactive material, within acceptable limits, to the environment.

**anticipated operational occurrences**: Conditions of normal operation expected to occur one or more times during the life of the facility and include, but are not limited to, loss of offsite power to the process activity within the facility.

**Authorization Agreement**: The document mutually agreed upon by the Office of River Protection Manager and a Contractor that specifies authorization terms and conditions.

**authorization basis**: The composite of information provided by a Contractor in response to radiological, nuclear, and process safety requirements that is the basis on which the DOE grants the Contractor permission to perform regulated activities.

**back-fit**: The addition, elimination, or modification of (1) structures, systems, or components of the facility or (2) procedures or organizations required to operate the facility after the construction authorization has been issued.

**catastrophic release**: A major uncontrolled chemical emission, fire, or explosion that presents serious danger to employees in the workplace.

**co-located worker**: An individual within the Hanford Site, beyond the Contractor-controlled area, performing work for or in conjunction with DOE or utilizing other Hanford Site facilities.

**common-cause failures**: Dependent failures that are caused by a condition external to a system or set of components that make system or multiple component failures more probable than multiple independent failures.

**common-mode failures**: Dependent failures caused by susceptibilities inherent in certain systems or components that make their failures more probable than multiple independent failures due to those components having the same design or design conditions that would result in the same level of degradation.

**Contractor**: The company or companies selected to contract with DOE for construction and operation of the technologies and facilities necessary to retrieve, process tank waste, and deliver treated waste products to DOE for storage or disposal.

**Contractor Representative(s)**: The organization manager(s), or duly appointed designee(s), who have direct Contract responsibility, accountability, and authority for directing or performing the River Protection Project Waste Treatment Plant work subject to the set of standards.

<sup>&</sup>lt;sup>3</sup> Certain terms used in this document and listed in this glossary have origins in radiological and nuclear safety. Extension of their use to process safety may be useful but is not specified herein. It is expected that the extension of their use to process safety will be considered as part of the standards and requirements identification process

Contractor Representative(s) recommended set of standards and requirements: Those standards and requirements identified through a DOE-specified process and recommended by the Contractor Representative(s) as necessary assurance that work will be performed in a manner that protects the workers, the public, and the environment from the actual hazards identified for the specific work activities of the River Protection Project Waste Treatment Plant Contractor. (Also see the definition for "requirements.") The recommended set serves as a basis for DOE review and approval by the ORP and the issuance of the Safety Requirements Document.

**control strategy**: A set of generally described provisions (barriers, dilution/dispersal, physical limitations on material quantities, administrative material controls, confinement, ventilation of flammable gas, etc.) and/or approaches (defense in depth, use of passive features, prevention, mitigation, etc.) which are intended to ensure adequate control of a specific hazard and associated accidents in the context of the work.

**controlled area**: The physical area enclosing the facility by a common perimeter (security fence). Access to this area can be controlled by the Contractor. The controlled area may include identified restricted areas.

**Deactivation Safety Evaluation Report**: The document approved and issued by the ORP that addresses the adequacy of the authorization basis for deactivation.

defense in depth: The fundamental principle underlying the safety technology of the facility centered on several levels of protection including successive barriers preventing the release of radioactive materials to the workplace or environment. Human aspects of defense in depth are considered to protect the integrity of the barriers, such as quality assurance, administrative controls, safety reviews, operating limits, personnel qualification and training, and safety program. Design provisions, including both those for normal facility systems and those for systems important to safety help to (1) prevent undue challenges to the integrity of the physical barriers; (2) prevent failure of a barrier if it is challenged; (3) where it exists, prevent consequential damage to multiple barriers in series; and (4) mitigate the consequences of accidents. Defense in depth helps to assure that two basic safety functions (controlling the process flow and confining the radioactive material) are preserved and that radioactive materials do not reach the worker, public, or the environment.

**design basis**: The information that identifies the specific functions to be performed by structures, systems, or components of the facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

design-basis events: Postulated events providing bounding conditions for establishing the performance requirements of structures, systems, and components that are necessary to (1) ensure the integrity of the safety boundaries protecting the worker; (2) place and maintain the facility in a safe state indefinitely; or (3) prevent or mitigate the event consequences so that the radiological exposures to the general public or the workers would not exceed appropriate limits. The design-basis events also establish the performance requirements of the structures, systems and components whose failure under design-basis event conditions could adversely affect any of the above functions.

**documented safety analysis:** A documented analysis of the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety.

**DOE-customer**: A DOE employee who has knowledge of the equipment, facilities, and processes necessary for performance by the Contractor of the work activities to deliver the contracted services.

**environment, safety, and health standards experts**: Individuals with knowledge and expertise relevant to the radiological, nuclear, or process standards and requirements in a particular environment, safety, and health discipline.

**facility**: Those buildings and equipment directed to a common purpose and those activities and supporting elements occurring at a single location.

**Final Safety Evaluation Report**: The document approved and issued by the ORP that addresses the adequacy of the authorization basis for operation.

**hazard**: A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard for the likelihood or credibility of accident scenarios or consequence mitigation).

hazards assessment experts: Individuals with the knowledge, skills, and abilities to identify, based on examination of the work activities defined, the hazards associated with the work activities, as well as the risk to the workers, public, and environment attributable to those hazards.

**hazards control experts**: Individuals with knowledge, skills, and abilities to identify, based on examination of the work activities and associated hazards, the controls necessary to mitigate the hazards to an acceptable level.

**highly hazardous chemical**: A substance possessing toxic, reactive, flammable, or explosive properties, which can lead to a catastrophic release.

**important to safety**: Structures, systems, and components that serve to provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the workers and the public. It encompasses the broad class of facility features addressed (not necessarily explicitly) in the top-level radiological, nuclear, and process safety standards and principles that contribute to the safe operation and protection of workers and the public during all phases and aspects of facility operations (i.e., normal operation as well as accident mitigation).

This definition includes not only those structures, systems, and components that perform safety functions and traditionally have been classified as safety class, safety-related or safety-grade, but also those that place frequent demands on or adversely affect the performance of safety functions if they fail or malfunction, i.e., support systems, subsystems, or components. Thus, these latter structures, systems, and components would be subject to applicable top-level radiological, nuclear, and process safety standards and principles to a degree commensurate with their

contribution to risk. In applying this definition, it is recognized that during the early stages of the design effort all significant systems interactions may not be identified and only the traditional interpretation of important to safety, i.e., safety-related may be practical. However, as the design matures and results from risk assessments identify vulnerabilities resulting from non-safety-related equipment, additional structures, systems, and components should be considered for inclusion within this definition.

**independent oversight**: Authorized oversight by bodies or groups having no financial, programmatic, or other direct interest in the activities or organizations under review and which are totally free of management relationships with those activities or organizations.

**independent oversight bodies**: Independent oversight bodies are those established organizations that have no financial, programmatic, or other direct interest in and are outside the management structure of the ORP. The independent oversight bodies include personnel qualified and skilled to critique, evaluate, and recommend that the safety regulatory oversight provided by the ORP of the Contractor is effective.

**Independent Review Team**: A group of individuals with the appropriate knowledge and expertise to review the recommended standards set for completeness, credibility, and adequacy before the standards are recommended by the Contractor Representative(s) to ORP.

**Initial Safety Evaluation Report**: The document, approved and issued by the ORP, that addresses the capability or potential for obtaining future authorizations for construction, operation, and deactivation.

**Integrated Safety Management Plan Evaluation Report**: The document, approved and issued by the ORP, that addresses the adequacy of the Contractor's Integrated Safety Management Program as reflected in its Integrated Safety Management Plan.

**Integrated Safety Management Program**: A set of integrated activities that is directed toward the management or control of radiological, nuclear, and process hazards such that adequate protection is provided to workers, the public, and the environment.

**limiting conditions for operations**: The limits that represent the lowest functional capability or performance level of important-to-safety structures, systems, and components required for safe operations.

**limiting control settings**: The settings on important-to-safety systems that control process variables to prevent exceeding a safety limit.

margin of safety: The level of confidence that is assigned to the integrity of radiological control measures such as confinement barriers. It is defined as the range between the design acceptance limits and the design failure point of the control feature. The design acceptance limits for radiological control measures such as confinement barriers are established during the design of the facility. These criteria are given in terms of those physical parameters that define their performance. Whenever the values of the design acceptance limits are exceeded, the margin of safety, and therefore the confidence in the integrity of the control feature, is decreased.

**normal operation**: Steady-state operation and those departures from steady-state operation that are expected frequently or regularly in the course of facility operation, system testing, and maintenance. It includes conditions such as startup, shutdown, standby, anticipated operational occurrences, operation with specific equipment out of service as permitted by the approved operational constraints, and routine inspection, testing, and maintenance of components and systems during any of these conditions if it is consistent with the approved operational constraints.

**Office of Safety Regulation**: The organization that executes safety regulatory authority for the River Protection Project Waste Treatment Plant Contractor.

**offsite**: The area outside the perimeter of the Hanford Site.

**onsite**: The area within the Hanford Site control perimeter that is under the jurisdiction of the DOE.

**operating limits:** Those limits required to ensure the safe operation of a nuclear facility, including limiting control settings and limited conditions of operation.

**oversight safety determination**: The oversight of the Contractor performed by the Office of Safety Regulation to ensure continuing compliance to an authorization agreement.

**postulated accidents**: Events, including the design-basis events, that would have an adverse affect on the facility process but which do not have a significant probability of occurrence during the life of the facility and include, but are not limited to, pipe or tank failures.

**Preliminary Safety Evaluation Report**: The document, approved and issued by the ORP, that addresses the adequacy of the authorization basis for construction.

**process**: Any activity involving a highly hazardous chemical including use, storage, manufacturing, handling, or the onsite movement of such chemicals, or a combination of these activities.

**process manager**: A person, designated by the Contractor Representative(s), responsible for ensuring that the process steps are accomplished.

**Process Management Team**: A group of individuals designated by the Contractor Representative(s) to approve specified actions proposed by the process manager and to monitor their implementation.

**process safety**: The operation of facilities that handle, use, process, or store chemicals or hazardous materials in a manner free of episodic or catastrophic releases. However, the handling, use, processing, and storage of chemicals or materials with inherent hazardous properties can never be done in the total absence of risk. Process safety is an ideal condition towards which one strives.

**process safety management**: The application of management systems to the identification, understanding, and control of process hazards to prevent process-related injuries and incidents.

public: Individuals who are not occupationally engaged at the Hanford Site.

**radiation worker**: A worker who has qualifications and training to work in a restricted area of the facility where radiation or radioactive material is present.

**reliability targets**: Quantified probabilistic expectations that a component, equipment, or system will perform its intended function satisfactorily under given circumstances, such as environmental conditions, limitations as to operation time, and frequency and thoroughness of maintenance for a specified period of time. Identified important-to-safety items are expected to perform their function satisfactorily through all design basis accident conditions.

**requirements**: Standards that are mandated by an authority through statute, regulation, or contract.

**restricted area**: An area identified by the Contractor to which access is limited for the purposes of protecting individuals against undue risk from exposure to radiation and radioactive materials. Only a radiation worker is allowed into this area.

**risk analysis**: The development of a qualitative or quantitative estimate of risk based on engineering evaluation and techniques for considering estimates of incident consequences and frequency.

**safe state**: A situation in which the facility process has been rendered safe and no pressurized material flow occurs in the process lines. Any active, energy generating, process reactions are in controlled or passive equipment. The structures, systems, and components necessary to reach and maintain this condition are functioning in a stable manner, with all process parameters within normal safe state ranges.

**Safety Analysis Report**: A document that fully describes the analyzed safety basis for the facility (safety envelope), fully demonstrates that the facility will perform and will be operated such that radiological, nuclear, and process safety requirements are met, and fully demonstrates adequate protection of the public, the workers, and the environment.

**safety assurance**: Established confidence that adequate protection of worker and public health and safety have been provided.

**safety basis**: The combination of information relating to the control of hazards at a nuclear facility (including design, engineering analyses, and administrative controls) upon which the DOE depends for its conclusion that activities at the facility can be conducted safely.

**safety function**: Any function that is necessary to ensure (1) the integrity of the boundaries retaining the radioactive materials, (2) the capability to place and maintain the facility in a safe state, or (3) the capability to prevent or mitigate the consequences of facility conditions that could result in radiological exposures to the general public or workers in excess of appropriate limits.

**safety limits**: Limits on process variables associated with those physical barriers, generally passive, that are necessary for the intended facility safety functions and that are found to be required to prevent release of unacceptable levels of radioactive material to workers or the general public.

**Safety Requirements Document**: A document that contains the approved and mandated set of radiological, nuclear, and process safety standards and requirements which, if implemented, provides adequate protection of workers, the public, and the environment against the hazards associated with the operation of the Contractor's facilities.

**Safety Requirements Document Evaluation Report**: The document approved and issued by the ORP that addresses the adequacy of the set of radiological, nuclear, and process safety standards that a Contractor proposes to implement to ensure adequate protection of worker and public health and safety.

safety setpoints: Physical parameters set in the control equipment by an operator for equipment that controls the process or process flow to maintain the process within the systems design safety limits. A safety setpoint represents a process characteristic, such as pressure, temperature, or material level, that is monitored by a control system to restrict the process characteristic within a system's design operating range. These setpoints are identified in the design as levels above which a process physical parameter would exceed a design operating range of a process component or system leading to its failure and risk to the safety of the worker, public, or the environment. Several setpoints may be used to initiate alarm levels or control the process to a safe state.

**significantly new safety information**: Either (1) a safety requirement newly mandated by the Office of Safety Regulation, (2) a safety item newly identified by the Contractor as an item not included in the Safety Analysis Report for the facility; or (3) a determination that an unresolved safety question exists.

**stakeholder**: Any individual other than federal employees or DOE contractor employees who will be materially affected by, or can materially affect, the outcome of the work, either favorably or unfavorably.

**standards**: The expressed expectation for the performance of work.

**state-of-the-art human factors**: The most effective design approaches established for use at the start of the final design phase.

**technical safety requirements**: The limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and hazards identified in the documented safety analysis for the facility: safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

Unreviewed Safety Question: A situation where (1) the probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analyses could be increased; (2) the possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analyses could be created; (3) a margin of safety could be reduced; or (4) the documented safety analysis may not be bounding or may be otherwise inadequate. (Also see definition for "margin of safety.")

work: Functional description of a set of activities (e.g., process operations) that will produce the intended outcome or objective (such as achieving a mission in terms of specified functional requirements).

worker: Worker means an individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities.

work activities: All activities associated with performing the work, including design, construction, operation, and deactivation.

work activity experts: Individuals with knowledge and expertise relevant to the work, site, and activities addressed by the standards set.